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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/839,778
Filing Date: April 20, 2001
Appellant(s): HERRON ET AL.

Brick Power
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 17, 2005 appealing from the Office action mailed November 17, 2004.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellants' statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellants' statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,747,274	Jackowski	5-1998
4,224,304	Sawai et al.	9-1980

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claims 1-6, 8-9, 11, 13-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Jackowski, 5,747,274. Jackowski discloses a method for performing an assay, comprising: substantially simultaneously evaluating the presence of a plurality of analytes in a sample, at least one analyte having known parameters indicative of an acute metabolic or disease state, see column 4, lines 32 - column 8, line 31, and column 19, lines 8-14; substantially simultaneously determining concentrations of each of the analytes, col. 29, lines 31-39; continuing the determination until the analyte has been reliably determined to be present in an amount indicative of the metabolic or disease state, see column 29, lines 51-63; and reporting said determination in an amount indicative of the metabolic or disease state, see column 29, lines 51-63.

As to claim 2, evaluating the presence of at least one other analyte continues after the report in order to accurately determine the presence or concentration of the analyte, see column 22, lines 1-12.

As to claim 3, the method further comprises evaluating binding of the analytes to corresponding reactive elements over a plurality of time points, see column 22, lines 6-12.

As to claim 4, the determination is effected by reacting at least one analyte with a corresponding reactive element, see column 19 lines 15-22.

As to claim 5, the determination includes exposing the sample to the reactive elements, see column 11, lines 1-12.

As to claim 6, each reactive element is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 8, the reactive elements are arranged in a pattern on the waveguide surface, (col. 30, line 67, col. 31, lines 8-9, and lines 15-16, see figure 10, disclosing the arrangement of the antibodies, i.e., reactive elements.)

As to claim 9, the determination includes introducing a light beam including at least one wavelength for stimulating a light signal from the reactive element when the reactive element has coupled with the analyte, see column 27, lines 38-58, and column 29, lines 1-27.

As to claim 11, the determination includes measuring the light signal generated from the reaction of the analyte with the reactive element, see column 27, lines 37 column 28, line 11.

As to claim 13, the analyte is a marker released from cardiac tissue only after a myocardial infarction, see column 1, lines 63-67.

As to claim 14, the marker comprises myoglobin, see column 4, line 36-5.

As to claim 15, the analyte is a cardiac specific marker, see column 1, lines 63-67.

As to claims16-19, the analyte comprises troponin as claimed, see column 7, lines 34-37.

As to claim 20, the analyte comprises creatine kinase, see column 5, lines 29-31.

As to claim 21, the creatine kinase comprises CK-MB, see column 5, lines 29-31.

(b) Claims 7 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski, 5,747,274, in view of Sawai et al., 4,224,304.

Jackowski discloses the invention substantially as claimed (see above.) Jackowski provides several examples of methods to determine the extent or amount of binding between the antibodies and markers (see for example, col. 28, lines 8-38.) Jackowski teaches that other methods for determining the presence and amount of a marker or analyte may be used in the invention (col. 29, lines 31-36.)

However, Jackowski does not disclose that the continuation step includes correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte (claims 7 and 12); nor that the light signal is indicative of a rate of reaction between the analyte of interest and the reactive element (claims 10 and 11.)

Sawai et al., 4,224,304, discloses a method for quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time (col. 11, lines 36-44.) This method is a method of correlating a rate of reaction between the analyte and the reactive element to a concentration of the analyte, as well as a method wherein the light signal is indicative of a rate of reaction between the analyte and the reactive element as claimed by Appellants.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the Sawai method as the method of determining the amount of analyte binding that is generally taught by Jackowski because Sawai teaches that it is a known method for determining the extent or amount of binding (and Jackowski teaches that known methods for determining binding may be used.) In view of the teachings of Jackowski and Sawai, one of ordinary skill in the art would have a reasonable expectation of success.

(10) Response to Argument

Appellants' arguments in the brief are considered but are not persuasive for the reasons set forth below.

On page 7 of Appellants' brief, Appellants assert that as used in Jackowski, the term "simultaneous" does not have its ordinary meaning or that used in the specification of the present application. Appellants state that, as indicated at column 22, lines 2-19, the term "simultaneous" is not used in Jackowski to indicate that analysis of different

analytes occurs concurrently, but that the analysis occurs within a given period of time (e.g., thirty minutes) and that each analysis is performed on part of the same sample.

These argument are not persuasive. The term "simultaneous" as used by Jackowski at column 22, lines 2-19 does not exclude concurrent analysis. Column 22, line 6-12 states that 'the term "simultaneous does not mean that the analysis for each marker must be done concurrently, but such analysis must be done within a time frame (e.g., within about one-half hour following sampling) so that the relative level of each marker can be assessed, and this information used to diagnose the cause of chest pain. Although Jackowski states that "simultaneous" does not have to mean concurrent, Jackowski is not excluding it to mean concurrent. Moreover, the term "simultaneous" as used by Jackowski encompasses a concurrent evaluation of the sample, because Jackowski indicates that the term "simultaneous" includes an evaluation within a given period of time (col. 22, lines 8-9), and a concurrent evaluation is within a given period of time.

Furthermore, Appellants' arguments assume that Appellant's claims are limited to concurrent analysis. However, the Office interprets Appellants' claim to encompass more than concurrent analysis. Appellants are claiming "**substantially** simultaneous" (emphasis added), which indicates that the evaluation need not be concurrently performed. Rather, Appellants' claims encompass an evaluation that is staggered over a short time period. Therefore, the scope of Appellants' claims encompass the invention of Jackowski.

Appellants also point out that figures 8 through 10 of Jackowksi provide an example of a multi-analyte assay and the sample is assayed for each analyte at a different point in time, depending upon the time it takes the sample to wick or travel by capillary action along a membrane to which the sample is applied and upon which the labeled markers are immobilized.

For the same reasons as set forth above, Appellants' argument here is not persuasive. Appellants' claims are not limited to concurrent assays and the description of the embodiment as shown in figures 8 through 10 of Jackowski show a *substantially* simultaneous assay. Appellants' claims read on this embodiment disclosed by Jackowski because Appellants' claims recite "substantially simultaneous". Moreover, Figures 8 through 10 of Jackowski is only one disclosed embodiment. Jackowski in column 25, lines 39-44 discloses other types of solid supports such as test tube walls, beads, paper, etc. These solid supports do not necessarily require wicking or travel by capillary action.

Furthermore, Jackowski at column 25, lines 45-48, discloses that in another embodiment, the markers are analyzed by the placement of portions of the sample within separate tubes or solid support materials, each containing individual detector antibodies for detection of the markers. Such an embodiment certainly allows for concurrent assays to be performed. There is no teaching by Jackowski that the assays of the different markers must be staggered.

Likewise, Jackowski further teaches at column 25, lines 49-51, that alternatively, if each of the detector antibodies are labeled differently, then the test can be performed

in a single tube. Such an embodiment to carry out the method of use disclosed by Jackowski shows that the markers can be concurrently assayed, or at the least, substantially simultaneously assayed.

Appellants also argue on page 9 that Jackowski does not anticipate several elements of claim 1. Appellants argue that Jackowski does not describe "*continuing* a substantially simultaneous determination" of the presence of at least one analyte in a sample "*until* the at least one analyte has been reliably determined to be present in an amount indicative of a metabolic or disease state..." (emphasis added.) Appellants argue that, stated another way, the kinetics of the binding reactions are evaluated to provide an accurate determination of whether or not one or more analytes is present in a sample and, optionally, the amount of each evaluated analyte in the sample. Appellants assert that the description of Jackowski in contrast is limited to less accurate "end point" assay techniques, where the amount of each analyte in a sample is determined at a single point in time.

This argument is not persuasive because claim 1 does not require that the kinetics of the binding reactions be evaluated to provide an accurate determination of the presence, and optionally, the amount of an analyte. Thus, claim 1 does not exclude the assay disclosed by Jackowski. The assay of Jackoswki is continued until an analyte has been determined to be present in an amount indicative of a disease state. In particular, Jackowski teaches in column 9, lines 1-2, that the presence and amount of a particular marker is detected. Similary, Jackowski teaches in column 29, lines 35-36 that the invention comprises detection of the presence and amount of the markers.

Likewise, Jackowski teaches in column 32, lines 28-29 that, for example, a color change is proportional to the concentration of the cardiac marker in the sample. Jackowski in column 29, lines 56-58, for example, teaches that the markers indicate myocardial infarction for example. Thus, Jackowski teaches continuing the assay until an analyte has been determined to be present in an amount indicative of a disease state.

Appellants further argue on page 10 that Jackowski does not expressly or inherently describe that multiple analytes of a sample may be substantially simultaneously evaluated. Appellants argue that with respect to the current invention, the analytes are evaluated at substantially the same time, or substantially concurrently, as described in the specification at paragraphs [0072], [0078] and in particular [0121] of the present application. Appellants also argue that for the same reasons, Jackowski does not expressly or inherently describe or anticipated "substantially simultaneously determining concentrations of each of the analytes. This argument is not persuasive for the reasons set forth above regarding the term "simultaneous".

Appellants also argue on page 11 that claim 2 is additionally allowable because Jackowski does not disclose that "evaluating the presence of at least one other analyte in [a] sample" may continue after a report of a reliable determination that at least one analyte in the sample is present in an amount which is indicative of a metabolic or disease state. This is not persuasive because Jackowski teaches that detection of the markers may be done within a time frame, i.e., one marker after another (see column 22, lines 1-12.)

Appellants additionally argue that claim 8 is also allowable because Jackowski does not teach that a substantially simultaneous determination of the presence of at least one analyte in a sample may be effected by reacting at least one analyte in a sample with a corresponding reactive element, the corresponding reactive element being one of a plurality of reactive elements that are arranged in one or more patterns on the surface of a waveguide. This is not persuasive because Jackowski teaches that the immunoassay format may incorporate optoelectronic detection systems including fiber optic waveguide techniques for example (see col. 27, lines 42-49, and col. 29, col. 1-27, and column 28, lines 1-4, and column 29, lines 5-15). Moreover, Jackowski specifically discloses several embodiment with a discrete arrangement of antibodies (see col. 31, lines 1-21, and col. 33, lines 43-45 and lines 56-60). (The Office notes that the claimed reactive elements are the reactive sites of the antibodies which bind to the analytes.) Jackowski thus teaches reacting an analyte in a sample with a corresponding reactive element, wherein there are a plurality of reactive elements arranged in a pattern on waveguide.

Appellants also argue on page 13 that with respect to claims 7 and 10-12, which are rejected under 35 U.S.C. 103(a), that neither Jackowski nor Sawai teaches or suggests a technique for assaying a sample for multiple analytes *simultaneously*. Appellants further argue that for this same reason, the combined teachings of Jackowski and Sawai do not teach or suggest each and every element of independent claim 1, from which each of claims 7 and 10-12 depends. This argument is not persuasive for the reasons set forth above regarding the term "simultaneous".

Appellants also argue on page 13 that Jackowski and Sawai both lack any teaching or suggestion of stimulating a light signal from a reactive element, which is indicative of a rate of reaction between the analyte of interest and the type of reactive element from which the light signal is stimulated, as required by claim 10. This is not persuasive because Sawai discloses this limitation by teaching a method for quantitative determination of antigens in a sample by evaluating the rate of increase in absorbance or percent absorption per unit time (col. 11, lines 36-44.)

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

A.L.

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